JAN - 5 2012

510(K) SUMMARY OF SAFETY & EFFECTIVENESS
BÂRRX's HALO^{60} Ablation Catheter

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

BÂRRX Medical, Inc.
540 Oakmead Parkway
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Contact: Dawn Chang, Regulatory Affairs Manager
Date Prepared: August 24, 2011

NAME OF SUBJECT DEVICE AND NAME/ADDRESS OF SPONSOR

HALO^{60} Ablation Catheter (model 90-9300)
BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

ESTABLISHMENT REGISTRATION NUMBER

3004904811

COMMON OR USUAL NAME

Electrosurgical Coagulation Catheter

REGULATION DESCRIPTION

Electrosurgical Cutting and Coagulation Devices and Accessories (21 CFR 878.4400, Product Code GEI)

PREDICATE DEVICE

HALO^{90} Ablation Catheter (model 90-9100, cleared by the FDA under K093008, K083737, and K062723).

OVERVIEW

The HALO^{60} Ablation Catheter (subject device, hereafter referred to as "HALO^{60}") is a single-use bipolar device that delivers radiofrequency energy to the treatment tissue within the gastrointestinal tract through a copper electrode. The HALO^{60} is a modification of the HALO^{90} Ablation Catheter (predicate device, cleared by the FDA under K093008, K083737, and K062723, hereafter referred to as "HALO^{90}"). The

primary modification is a dimensional reduction of the copper electrode surface area, from 2.6cm^2 (1.3cm x 2.0cm, HALO^{90}) to 1.5cm^2 (1.0cm x 1.5cm, HALO^{60}). Secondary modifications include dimensional reduction of the copper electrode supporting components.

The electrode surface area of the subject device is reduced to approximately 60% of the predicate device, hence the product name HALO^{60}. This new product provides an option for physicians to treat smaller diseased area. The modification neither changes the intended use nor alters the fundamental scientific technology of the original device; therefore this submission is a Special 510(k).

DEVICE DESCRIPTION

The HALO^{60} (subject device) is a single-use bipolar device that delivers radiofrequency energy to the treatment tissue within the gastrointestinal tract. It is used solely with the HALO^{FLEX} Energy Generator (model 1190A-115A), which provides the radiofrequency energy.

PRINCIPLES OF OPERATION

Same as the HALO^{90}, the HALO^{60} is connected to the HALO^{FLEX} Energy Generator using an output cable. Once connected, the Generator will recognize the catheter based on a unique ID and set the appropriate power density and energy density range.

The HALO^{60} is introduced into the esophagus under endoscopic visualization. Once the targeted treatment area is identified, the catheter electrode is positioned against the tissue by deflecting the endoscope. The energy activation is performed by depressing either a front panel switch on the generator or the foot-pedal. After the energy is delivered, the coagulation effect can be verified endoscopically.

INDICATION FOR USE STATEMENT

The HALO^{60} Ablation Catheter (used with the HALO^{FLEX} Energy Generator, model 1190A-115A) is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

SUBSTANTIAL EQUIVALENCE DISCUSSION

As mentioned earlier, the HALO^{60} (subject device) is a modification of the HALO^{90} (predicate device), cleared by the FDA under K093008, K083737, and K062723. The primary modification is a dimensional reduction of the copper electrode surface area, from 2.6cm^2 (1.3cm x 2.0cm, HALO^{90}) to 1.5cm^2 (1.0cm x 1.5cm, HALO^{60}) and the secondary modifications include dimensional reduction of the copper electrode supporting components. There is no change in the materials, amount of energy being delivered and the depth of the tissue being treated.

Both the subject and the predicate devices have the same intended use and fundamental scientific technology. Both devices are compatible with the HALO^{FLEX} Energy Generator. No changes have been made to the HALO^{FLEX} Energy Generator software in order to accommodate the HALO^{60}.

SUMMARY OF DESIGN CONTROL ACTIVITIES

Failure Modes, Effects, and Criticality Analysis (FMECA) was used to analyze the risks associated with the design modification. Design verification activities demonstrate that the design outputs of the modified device meet the design input requirements.

CONCLUSION

In summary, the company's HALO^{60} Ablation Catheter has the same intended use as all of the previously cleared HALO^{90} Ablation Catheter (K093008, K083737, K062723). In addition, the HALO^{60} Ablation Catheter has identical indications, technological characteristics, and principles of operation as its predicate devices.

The minor differences between the HALO^{60} Ablation Catheter model 90-9300 and its predicate device HALO^{90} Ablation Catheter model 90-9100 do not raise new questions of safety or effectiveness. Thus, the HALO^{60} Ablation Catheter model 90-9300 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Dawn Chang
Regulatory Affairs Manager
BÂRRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

JAN - 5 2012

Re: K112454
Trade/Device Name: HALO^{60} Ablation Catheter, Model 90-9300
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Codes: GEI, KNS
Dated: December 8, 2011
Received: December 9, 2011

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Benjamin R. Fisher, Ph.D., Director
Division of Reproductive, Gastro-Renal, and
Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112454

Device Name:

- HALO^{60} Ablation Catheter model 90-9300

Indications for Use:

The HALO^{60} Ablation Catheter (used with the HALO^{FLEX} Energy Generator, model 1190A-115A) is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

Prescription Use _X_ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112454